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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/802,627	03/17/2004	Igor Rukhman	1662/63303	4926
26646 7	590 03/08/2006		EXAMINER	
KENYON & KENYON LLP			CHUNG, SUSANNAH LEE	
ONE BROADWAY NEW YORK, NY 10004			ART UNIT	PAPER NUMBER
,			1626	
			DATE MAILED: 03/08/200	5

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
Office Action Summary		10/802,627	RUKHMAN ET A	RUKHMAN ET AL.			
		Examiner	Art Unit				
		Susannah Chung	1626				
The M. Period for Reply	AILING DATE of this communication app	ears on the cover sheet w	vith the correspondence a	ddress			
WHICHEVER - Extensions of tim after SIX (6) MO - If NO period for r - Failure to reply w Any reply receive	ED STATUTORY PERIOD FOR REPLY IS LONGER, FROM THE MAILING DATE in may be available under the provisions of 37 CFR 1.13 NTHS from the mailing date of this communication. The specified above, the maximum statutory period within the set or extended period for reply will, by statute, and by the Office later than three months after the mailing rm adjustment. See 37 CFR 1.704(b).	TE OF THIS COMMUN 6(a). In no event, however, may a ill apply and will expire SIX (6) MC cause the application to become A	IICATION. a reply be timely filed DNTHS from the mailing date of this of ABANDONED (35 U.S.C. § 133).	,			
Status							
1)⊠ Respon	sive to communication(s) filed on 03 Fe	bruary 2006					
2a)⊠ This act		action is non-final.		•			
<u>'=</u>	<u></u>						
• .	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of C	·						
4)⊠ Claim(s	4)⊠ Claim(s) <u>1,3-6,9,12-14,17,81 and 82</u> is/are pending in the application.						
•	4a) Of the above claim(s) <u>1,3-6,9,12-14,81 and 82</u> is/are withdrawn from consideration.						
	Claim(s) is/are allowed.						
· <u>-</u>	Claim(s) is/are rejected.						
· ·	,						
) are subject to restriction and/or	election requirement.					
Application Pape	ers						
· · · <u> </u>	cification is objected to by the Examine						
·	•		hy the Examiner				
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
	ment drawing sheet(s) including the correcti			FR 1.121(d).			
	or declaration is objected to by the Ex	·	• • •	• •			
Priority under 35	U.S.C. § 119						
12) Acknowl	edgment is made of a claim for foreign	priority under 35 U.S.C.	§ 119(a)-(d) or (f).				
a)∏ All t	a) All b) Some * c) None of:						
	2. Certified copies of the priority documents have been received in Application No						
_	opies of the certified copies of the prior		n received in this National	l Stage			
	pplication from the International Bureau						
* See the a	attached detailed Office action for a list of	of the certified copies no	t received.				
Attachment(s)							
	ences Cited (PTO-892)	4) Interview	Summary (PTO-413)				
	person's Patent Drawing Review (PTO-948) closure Statement(s) (PTO-1449 or PTO/SB/08)		o(s)/Mail Date Informal Patent Application (PT	O-152)			
Paper No(s)/Ma		6) Other:					

DETAILED ACTION

Claim 17 is pending in the instant application. Claims 2, 7, 10, 11, 15, 16, 18, 19-80 and 83-85 are canceled. Claims 1, 3-6, 8-9, 12-14, 81 and 82 are withdrawn as being drawn to non-elected subject matter.

Response

Applicant's Remarks and amendment to the claims filed on 12/19/2005 are acknowledged.

Claim 17 stands rejected under 35 USC 103 as obvious over U.S. Pat. No. 5,399,578 (`578 Patent). Claim 17 is directed to an "amorphous form of valsartan, wherein the amorphous form has a DSC thermogram that lacks a melting point above about 1 J/g."

Applicants state the following:

As the Examiner is aware, melting is the thermal disordering of a crystalline latice. Therefore crystalline solids generally exhibit a melting point (some crystalline solids decompose before melting). However, the solid of the present invention, being purely amorphous, does not have any crystalline order. Therefore does not melt, and does not have a melting point. This lack of a melting point is demonstrated in the lack of any endothermic peak present in the DSC thermogram, Figure 3. (Since melting takes thermal energy, one would expect to see an endothermic peak at the melting point.)

According to the Office Action, the '578 patent discloses valsartan with a melting point of 105 to 115°C. ('578 patent, col. 34, 1. 62). Because it exhibited a melting point, that valsartan was at least partially crystalline, and not completely amorphous.

It is true that crystalline solids generally exhibit a melting point, but it is also true that solids exhibit a melting point. The amorphous form, which is described by applicant as being devoid of crystalline structure, will also exhibit a melting point. The `578 Patent discloses an amorphous form with melting points. Unless applicant can demonstrate a patentable difference with the `578 Patent the instant claim is obvious in view of it.

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An amorphous form of a compound is a solid in which there is no long-range order of the positions of the atoms. (Solids in which there is long-range atomic order are called crystalline solids.) Most classes of solid materials can be found or prepared in an amorphous form. Therefore, it is difficult to distinguish between amorphous forms because by their very nature there is no order to the position of the atoms and replication of amorphous forms will probably include variations based on methods of preparation, levels of impurity, amount of water, etc....

It should be noted that generally melting point is not a good measure of patentability because it varies greatly depending on the amount of impurity, water, etc... In addition, no patentable weight will be given to melting point unless a clear side-by-side comparison is done distinguishing the two compounds, i.e. showing the patentable aspect of the compound. Based on the data provided, it appears that one skilled in the art could produce the same amorphous form of the instant application, utilizing the methods disclosed in the `578 Patent.

Therefore, the instant claim, which discloses an amorphous form of valsartan, but not the melting point, is not allowable in view of the `578 Patent which also discloses an amorphous form of valsartan with the melting point.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susannah Chung

Patent Examiner, AU 1626

Date: 03/01/2006

KAMAL A. SAEED, PH.D. PRIMARY EXAMINER

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